Pharma Proofreading: Artwork vs. Text Team Responsibility

By Adrien Laurent, CEO at IntuitionLabs • 11/24/2025 • 35 min read

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Executive Summary

In the highly regulated pharmaceutical industry, the final proofreading of packaging and labeling materials is a critical quality control step. Ensuring **accuracy** in pharmaceutical labeling is non-negotiable: even minor errors (e.g. a misplaced decimal point) can endanger patient safety and trigger costly recalls ([1] www.schlafenderhase.com) ([2] www.globalvision.co). This report examines the key question: *Who "owns" the proofreading step – the artwork (design) team or the text (content) team – in a modern pharma company?* Drawing on regulatory guidelines, industry practices, case examples, and technological trends, we find that **proofreading is inherently a shared, cross-functional responsibility** rather than exclusively owned by one department. Both the **content-originating teams (e.g. Regulatory Affairs, Medical Writing, Marketing, Legal)** and the **artwork/production teams** play essential roles in the proofreading process, with final oversight often residing in the Quality/QA organization.

Key findings include:

- **Multi-Team Workflow:** Pharmaceutical packaging approval typically involves many stakeholders (Regulatory Affairs, Medical/Scientific, Marketing, Legal, Design/Graphics, Production, QA, etc.). The content is usually drafted by regulatory or medical writing teams and then passed to design/artwork for layout. At least **two distinct proofing stages** often occur: an initial check by content experts, and a cross-check by artwork or QA teams ([3] www.schlafenderhase.com) ([4] www.gmpsop.com).
- **Regulatory vs. Artistic Duties:** Regulatory/RA teams provide the *approved "Editor's Copy"* of text and are primarily responsible for helping ensure content accuracy and compliance with legal labeling requirements ([5] www.freyrsolutions.com) ([4] www.gmpsop.com). Artwork/design teams then incorporate that copy into packaging templates, and they verify that no unintended changes arose during file conversion or layout ([6] www.gmpsop.com). Both sides conduct reviews: for example, one company had its artwork team proof its design and then have Regulatory Affairs proof it again, highlighting how responsibility is often **shared** ([3] www.schlafenderhase.com).
- **Quality Oversight:**Quality Assurance (QA) and Manufacturing/Packaging groups provide final sign-off. Regulatory Good Manufacturing Practice (GMP) regulations explicitly require that labeling materials be *"carefully examined for identity and conformity"* to approved content ([7] www.law.cornell.edu). The "Qualified Person" (in EU) or QA unit (in US) typically retains ultimate responsibility for the correctness of the final printed label, effectively overseeing the proofreading assurance.
- **Risk of Errors:** Labeling mistakes have frequently caused recalls. For example, labeling and artwork errors account for roughly **10–20% of drug/device recalls** ([8] packagingeurope.com) ([9] informait.com). More than **one in five** (20%) FDA drug recalls in 2022 were due to labeling or packaging errors ([9] informait.com). Industry analyses note that labeling errors remain a persistent problem – "the most common reason" for pharmaceutical recalls in recent years ([2] www.globalvision.co) – underscoring the need for robust review processes.
- **Automation and Tools:** Modern pharma firms increasingly employ automated proofreading and comparison tools to augment human review ([10] informait.com) ([11] www.schlafenderhase.com). Automated text-inspection and artwork-comparison systems dramatically reduce proofreading time and catch conversion glitches ([12] www.healthcarepackaging.com) ([13] informait.com). Case examples show major efficiency gains: one company cut a 3–7 hour manual label proofing task to just 1.25 hours using software ([12] www.healthcarepackaging.com), and AstraZeneca's adoption of automated comparison tools allowed faster reviews with higher confidence of error-free results ([14] www.schlafenderhase.com).

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- **Collaborative Governance:** The consensus among industry experts is that **no single department should bear sole ownership** of proofreading. Instead, best practices call for *shared responsibility* and clear governance models ([15] www.freyrsolutions.com) ([6] www.gmpsop.com). Cross-functional "proofreading" teams or centralized artwork management centers are emerging to coordinate reviews. Crucially, standardized SOPs and checklists (often enforced by quality systems) define the specific duties of each function in the proofreading workflow ([6] www.gmpsop.com) ([16] www.freyrsolutions.com).

- **Future Directions:** Technological advances (AI-assisted text generation, integrated regulatory content platforms, digital labeling) will continue to reshape this space. However, even as tools evolve, the fundamental need for human oversight remains. The future "owner" of proofreading is likely to be the **process itself** – orchestrated by validated digital systems under quality governance ([17] informait.com) ([18] appian.com).

In summary, the modern pharmaceutical proofreading step is a *harmonized quality gate* rather than the domain of a single team. Effective control of proofreading hinges on strong processes that involve both content and design experts (and quality oversight) working in tandem ([3] www.schlafenderhase.com)([6] www.gmpsop.com). The debate "Artwork vs. Text" is ultimately resolved by the acknowledgment that both are integral: content must be correct **and** packaging representation must be error-free. As one industry guideline bluntly concludes, *"In an industry where there's little to no room for error, setting up proper proofreading processes is of critical importance."* ([19] www.globalvision.co).

Introduction and Background

Pharmaceutical products are uniquely regulated. Every drug, biologic, or medical device must carry precise labeling information (active ingredients, strengths, dosage data, warnings, barcodes, etc.), and errors can have serious health implications ([20] pmc.ncbi.nlm.nih.gov) ([2] www.globalvision.co). To prevent mistakes, pharma companies implement multi-step development processes for packaging artwork and labels, typically defined in **Standard Operating Procedures (SOPs)**. The process begins with **approved content** (brand name, generic name, indications, instructions, etc.) assembled by regulatory, medical writing, or marketing teams. Designers ("artwork production" teams) then produce the final layouts on packaging templates. Each step includes checks for accuracy. Crucially, the **proofreading step** – a detailed final review of the complete artwork against the approved content – is a key gate before printing.

Historically, proofreading began as a manual task: producers would print proofs (hardcopy or PDFs) and multiple reviewers would **visually compare** them against source text ([21] www.healthcarepackaging.com). However, manual proofreading is labor-intensive and error-prone. In today's **global, multilingual supply chains**, a single product may have dozens of label variants (different markets and languages) and frequent content updates, further complicating proofreading ([22] informait.com) ([23] www.globalvision.co). An iconic example is a multilingual carton where a critical warning line was mistranslated or omitted during layout – such errors force production halts and recalls.

The introduction of digital tools has transformed the landscape. Automated proofreading systems, exampled by products like **GlobalVision** and **TVT**, can perform *pixel-to-pixel* or text-based comparisons between source and proof, greatly speeding up review and catching subtle discrepancies ([24] www.imageprovision.com) ([25] www.healthcarepackaging.com). Regulatory guidelines now often expect validated computer systems (21 CFR Part 11-compliant) in labeling workflows, and companies invest in integrated **label management systems** to ensure a single "source of truth" for product data ([26] www.freyrsolutions.com) ([27] appian.com). These trends mean that a modern proofing error may result less from human oversight than from process gaps or system misalignment.

Given this complexity, the question of *"who owns the proofreading step"* has gained attention in pharmaceutical circles. Is it the responsibility of the **"Artwork" (design) group** that creates the files? Or the **"Text" (content) side** (Regulatory Affairs, Labeling specialists) who author the information? Or ultimately the **Quality/Release**

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function that must sign off? We examine this question by analyzing regulatory requirements, organizational roles, and real-world practices, as detailed below.

The Pharmaceutical Packaging Workflow and Proofreading

Regulatory Framework

By law, all pharmaceutical labeling and packaging must adhere to stringent regulations. In the United States, rules are codified in **21 CFR**. For example, 21 CFR 211.125 requires that *"Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master… records."* ([7] www.law.cornell.edu). This GMC requirement implies that some qualified personnel (often in Quality Assurance) must review all labeling content carefully before printing. Multi-national companies also follow **EMA** guidelines (e.g. EU GMP Annex 16/13) which similarly demand dual checks of labeling content and physical appearance. Marketing Authorization Holders (MAHs) have legal responsibility to ensure all label text complies with the approved dossier, and local market regulations require precise formatting (e.g. Braille, IUCLID codes). Compliance is enforced by agencies: the FDA has issued thousands of warning letters and recalls for labeling violations, underscoring that "non-compliant artwork poses a risk to patient safety and may lead to a warning letter from the FDA, a product recall, and possibly legal and litigation costs" ([28] www.schlafenderhase.com).

Key Roles and Stakeholders

In practice, **pharma packaging development** is a multi-step, multi-department process. A typical workflow involves: (1) **Regulatory/Medical Writing** drafting the approved label content (Editor's Copy) and creating the initial specifications; (2) **Brand/Marketing** reviewing copy for brand messaging; (3) **Graphic Design/Artwork Studio** applying that copy into packaging templates; (4) **Quality Assurance (QA)/Packaging Operations** performing final checks and liaison with contract printers; (5) **Manufacturing/Supply Chain** typesetting barcodes and coordinating production.

Figure 1 (below) illustrates how text and artwork flows through these groups:

- **Regulatory Affairs (RA)/Labeling**: Develops and maintains the textual content, ensures compliance with global regulations. Acts as content owners and typically initiates label changes (new markets, updated claims, regulatory updates) ([5] www.freyrsolutions.com). They often create an *Editor's Copy (EC)* – the finalized text that will go into artwork.
- **Artwork/Graphics Team**: Takes the approved EC and produces the design file. Responsible for all **graphical and technical aspects** (dielines, fonts, color, barcodes). Their job includes internal checks that the artwork accurately reflects the text (no missing words, spacing issues, or graphical distortions) ([6] www.gmpsop.com). They assign version codes and lock the design file for printing.
- **Marketing/Brand Team**: Ensures packaging aligns with brand guidelines (layout, logos, imagery). They may also participate in content reviews, especially for promotional claims or product naming.
- **Legal/Compliance**: Reviews for overall legal compliance, accurate trademark use, and any litigation concerns on wording, at times overlapping with Regulatory review.
- **Quality Assurance (QA)**: Oversees the entire process to ensure SOPs are followed and, critically, *signs off on final printed materials*. In many companies, QA or the *Qualified Person* has ultimate authority to release packaging for distribution. QA enforces dual-review policies and manages deviations if errors occur.

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Because responsibilities overlap, dedicated **Labeling/Artwork Centers** or **workflows systems** are sometimes established. For example, Freyr Solutions notes that some firms place packaging artwork under Regulatory, others under Supply Chain or Packaging, but in reality *"it is a shared responsibility — a collaborative ecosystem that connects compliance, manufacturing, supply, and quality together."* ([29] www.freyrsolutions.com). The concept of a cross-functional artwork "Center of Excellence" has emerged to standardize this collaboration ([30] www.freyrsolutions.com).

Table 1 below summarizes the typical responsibilities of each stakeholder group in the proofreading workflow.

Stakeholder/Team	Role in Proofreading Process
Regulatory Affairs / Labeling	Prepares and approves the textual content. Reviews artwork to ensure all required drug information (dosage, ingredients, warnings, regulatory statements) is present and accurate against submissions. Acts as final authority on approved content ([5] www.freyrsolutions.com) ([4] www.gmpsop.com). Often provides the initial "Editor's Copy" and compares proofs to it.
Medical & Scientific Writers	Ensure technical accuracy of content (clinical data, pharmacology, usage instructions). May assist RA in verifying complex scientific phrasing and grammar.
Marketing/Brand Team	Verifies brand elements (logos, colors, imagery) and consumer-facing statements align with brand standards. Checks marketing claims and positioning are correct and consistent.
Graphic Design/Artwork Studio	Applies content to packaging templates. Prepares layout, graphics, barcodes, and final print files. Conducts an internal proof of design (ensuring no text or graphics are missing from the layout) ([6] www.gmpsop.com). For minor print-related adjustments (e.g. adding barcodes), may implement agreed changes without RA re-approval.
Quality Assurance (QA)	Oversees label approval SOPs. Reviews final proofs (often by comparing to approved master). Conducts sampling of printed labels and ensures conformance (per 21 CFR 211.125) ([7] www.law.cornell.edu). Holds ultimate responsibility for product release and often initiates investigations if discrepancies are found. Guardian of traceability and audit trail.
Packaging/Production	Provides technical specifications (dielines, materials). Checks printer proofs for color consistency and layout to ensure nothing is cut off or illegible. Executes final print runs and initial inspections.
Supply Chain/Operations	Verifies master data (component numbers, SKUs, serialization) is correct on labels. Ensures alignment with manufacturing systems (ERP/SAP). May check that corrected artwork matches updated product metadata.

Table 1: Key stakeholders in pharma labeling and their proofreading-related responsibilities (compiled from industry guidelines and best practices ([5] www.freyrsolutions.com) ([4] www.gmpsop.com)).

In summary, **no single stakeholder exclusively "owns" proofreading**. Each party checks aspects related to their expertise. The Regulatory/Text team owns content correctness, the Artwork team owns visual fidelity, and QA-owned processes bind it all together. This interplay is crucial: for example, if a graphic tool changes a character (e.g. the microgram symbol turning into "mg", a notorious conversion error) ([31] www.schlafenderhase.com), the artwork staff must detect it, but the regulatory team must approve the fix. SOPs therefore formalize dual checks: *"Market colleagues (Regulatory/Medical/Legal/Marketing) are responsible for proofreading the new or revised artwork against the Editor's Copy"*, including **character-by-character verification** of text and graphics ([4] www.gmpsop.com). Meanwhile, the artwork group independently reviews to confirm *"there are no omissions or changes from the EC"* ([6] www.gmpsop.com).

The Proofreading Step Defined

What exactly is the "proofreading" step? In pharma packaging, it means the thorough review of a **finalized packaging artwork proof** against the **approved reference content**. This includes checking every word and

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graphic element for accuracy. Key tasks in this step include:

- **Textual Verification:** Ensuring all label text (drug names, dosage, usage, warnings, etc.) matches the approved source information. This is literally a character-by-character comparison [see Table 5 below].
- **Content Completeness:** Confirming that all mandatory sections (danger symbols, expiry dates, lot numbers, batch numbers) are present and correctly placed.
- **Regulatory Compliance:** Verifying font sizes, intermediary warnings, language requirements, and other jurisdictional mandates.
- **Graphical and Barcode Checks:** Ensuring barcodes, logos, images, and color quality are correct. Each element must appear as intended without distortion or shift.
- **No Unapproved Changes:** Detecting any inadvertent changes introduced during layout (e.g. missing punctuation, shifted decimal points, wrong graphics).

Proofreading usually occurs in at least two stages. First, the **Regulatory/Text team** (often along with medical/marketing/legal reviewers) compares the **artwork draft** against the "Editor's Copy" to catch errors in transferring the content ([4] www.gmpsop.com). Then, after artwork revisions, the **Artwork/Production team** or **QA** performs a second review of the **final locked artwork file** (or printer proofs) against the last approved version ([6] www.gmpsop.com). This second review may involve both human eyeballs and/or automated comparison tools.

In effect, proofreading in pharma is akin to a rigorous *quality gate*: it is one of several mandatory checks before packaging goes to print. According to industry sources, failure anywhere along the workflow – whether by a medical writer, regulatory colleague, or designer – can let a typo slip through. For example, GlobalVision notes that even if "branding is off, consumers will likely still buy the medication," but a "misplaced decimal" can have *"severe consequences."* ([32] www.globalvision.co). Thus, every functional group must engage in proofreading to ensure *patient safety* and *regulatory compliance*.

Perspectives: Artwork Team vs. Text/Regulatory Team

The question frames proofreading as an **"Artwork vs. Text"** issue. This dichotomy implicitly pits two perspectives:

- **Text-Centric View:** Regulatory Affairs, Medical Writing, and Team believe that **text content** (the actual label copy) is paramount. They argue that since they originated the official wording, they should lead proofreading. After all, any content error (wrong dosage or missing warning) is usually a failure of this team. In practice, many companies require the Labeling Division to give final sign-off on wording, per QA instructions. The idea is that only those with full knowledge of regulatory requirements and the approved dossier can certify the text is correct. This view is reflected in guidelines like the GMP SOP (above) which declares that Market/Regulatory colleagues audit proof **character by character** ([4] www.gmpsop.com). As Freyr consultancy notes, RA teams "are the first to identify when a change must occur and initiate the corresponding artwork change control" ([33] www.freyrsolutions.com), implying they should also drive final checks.

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- **Artwork/Design-Centric View:** Graphic and packaging engineers feel that **layout and production** are critical to check. They point out that even perfect text can be ruined during file conversion or printing. For example, an artwork staffer may notice a font issue or a duplicated character that slipped in. They often have tools (such as PDF proofing or DTP proof readers) to automate checks on spatial consistency and fidelity – tasks text owners cannot easily do. From this angle, the question "Who owns proofreading?" is moot, because the artwork group will naturally inspect everything they lay out for mistakes. In some companies, the final patentability or branding sign-off is theirs. In globalVision's framework, artwork publication is a **collaborative** effort: after artwork is locked, the art center sends it to market colleagues, but then also *"review and approval of Printer Proofs… and assignment of identification number"* are by artwork staff ([34] www.gmpsop.com), indicating they consider final control of the file.

Both perspectives have merit. However, as Schlafender Hase points out, relying solely on manual checks by either side *"is not good enough anymore"* ([35] www.schlafenderhase.com). The fragmentation of processes – copy-paste steps, multiple PDFs, lack of version control – turns proofreading into a high-risk gap ([36] www.schlafenderhase.com). Misalignment can happen at each handoff: from Reg Affairs to drafting, to design, to print ([36] www.schlafenderhase.com).

Case Example: Dr. Max Pharma

A real-world example highlights this interplay. **Dr. Max Pharma** (a European generics/contract manufacturer) historically did *every* packaging proof manually: *first the artwork team* would independently proof their design, *then Regulatory Affairs* would proof it again ([3] www.schlafenderhase.com). This double-checking chain meant no single team took full ownership – both checked in series. The process was slow and still error-prone. When Dr. Max adopted an automated content-verification platform (TVT), they dramatically reduced the manual burden and error overlap: now both teams "reduced manual checks, transformed multi-language reviews, improved documentation, and increased team confidence" ([3] www.schlafenderhase.com). This case reveals a practical truth: **proofreading was formerly a shared chore, not an exclusive job, and even with sharing, errors persisted until workflows were tightened**.

Data and Evidence

Quantitative data underscore the stakes:

- **Recall Statistics:** According to FDA data, there were over *15,000* drug recalls in the U.S. from 2012–2023 ([37] www.lightfootlawdc.com). Many recalls are driven by labeling errors. For instance, in 2022, *over one in five* (20%) FDA drug recalls involved labeling or packaging mistakes ([9] informait.com). PackagingEurope reports that for medical devices ~9–10% of recalls are labeling-related (holding roughly steady since 2012) ([8] packagingeurope.com) ([38] packagingeurope.com). Similarly, GlobalVision analysis notes that recent leading FDA drug recalls are **"the most common reason from a packaging perspective"** ([2] www.globalvision.co). These figures demonstrate that proofreading failures frequently translate into recalls, with enormous costs: one source cites *$350,000* spent for each global labeling change, and individual recalls can waste millions of units ([8] packagingeurope.com).

- **Efficiency Gains via Technology:** Studies and industry reports illustrate how proper tools improve proofreading efficiency. ClinTrak (a clinical labeling service) reported that before automation, proofing a 19-panel booklet label could take 3–7 person-hours; after implementing GlobalVision's text-comparison software, the same task took only ~1.25 hours ([12] www.healthcarepackaging.com). The company also noted that the system caught small font spacing and foreign-character issues beyond human detection ([12] www.healthcarepackaging.com). A McKinsey analysis (cited in [23]) found that smart quality-control automation can reduce lead times in packaging workflows by up to 60–70%, and speed deviation resolution by 90% ([39] informait.com). At AstraZeneca, adoption of the TVT text/artwork comparison tool allowed "faster" proofreading *with confidence* of not missing mistakes ([14] www.schlafenderhase.com).

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- **Human vs. Automated Proofreading:** Comparative data illustrate continuing the shift to automation. GlobalVision's buyer guide provides feature comparisons (Table reproduced as Table 2) and highlights key manual limitations. For example, manual proofreading has *human variability* and takes hours per review, while an automated system is algorithmic, repeatable, and can do a document's review in minutes ([13] informait.com). Automated tools also build robust audit trails (critical for 21 CFR Part 11 and EU Annex 11 compliance) and scale easily with the volume of labels ([13] informait.com) ([40] informait.com). The trade-off is losing some contextual insight – but in life sciences the consensus is that *combined approaches* (machine checking augmented by expert judgment) yield the best results.

Table 2 contrasts manual and automated proofreading approaches, summarizing industry insights:

Criterion	Manual Proofreading	Automated Proofreading
Speed	Very time-consuming (hours per file) ([13] informait.com)	Rapid comparison (minutes per file) ([13] informait.com)
Consistency	Reviewer-dependent; performance can vary (fatigue) ([13] informait.com)	Algorithmic; uniform accuracy across runs ([13] informait.com)
Audit Trail / Defensibility	Minimal or fragmented (notes on handouts)	Full, timestamped comparisons; 21 CFR Part 11 compliant output ([13] informait.com)
Scalability	Linear with staff; bottlenecks with volume	Parallel processing; easily scales to many SKUs/languages ([13] informait.com)
Error Detection	Contextual judgment; may miss subtle shifts (esp. multilanguage/graphics) ([31] www.schlafenderhase.com)	Detects every character/graphic change (pixel-to-pixel, OCR-based) ([24] www.imageprovision.com) ([12] www.healthcarepackaging.com)
Special Challenges	Prone to oversight (blind spots, complexity overload) ([1] www.schlafenderhase.com)	Requires proper integration and validation (source data integration) ([41] informait.com) ([27] appian.com)

Table 2: Comparison of manual vs. automated proofreading in pharma packaging (from industry analyses ([24] www.imageprovision.com) ([13] informait.com)).

This evidence suggests that modern pharmaceutical companies are moving toward automated or semi-automated proofing within integrated workflows ([10] informait.com) ([3] www.schlafenderhase.com). Nonetheless, automation is not yet universal. Many smaller or legacy organizations still rely heavily on manual reviewers (often expensive PhD-level regulatory writers) for proofreading labor ([42] www.schlafenderhase.com), while the remainder of the industry invests in systems to reduce that burden.

Case Studies and Real-World Examples

Dr. Max Pharma (Cross-Functional Collaboration)

As detailed above, Dr. Max Pharma's workflow evolution exemplifies the interplay of text and artwork teams. By tasking both the artwork department and the regulatory department to proof each label, the company ensured multiple eyes on each label ([3] www.schlafenderhase.com). Yet even this 2-person proofreading chain was cumbersome. After adopting a digital "Content Verification Platform," Dr. Max noted a transformation: **"they reduced manual checks, transformed multi-language reviews, improved documentation, and increased team confidence"** ([3] www.schlafenderhase.com). This result – eliminating duplicate manual effort without sacrificing accuracy – highlights how both teams sharing the proofreading load can be made efficient through the right tools.

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AstraZeneca (Automation Improves Confidence)

AstraZeneca provides a global-scale example of integrating proofreading into standardized workflows. As part of their Labeling SOPs, AZ implemented the TVT comparison software to manage *Core Product Information* and *Global Labeling* updates across many markets. Senior manager Martin Rous reports: *"Since implementing TVT along with the TVT Artwork module, we can be more confident of our results, and that means less stress for our proofreaders. We can also do the job faster – confident we won't miss any mistakes."* ([14] www.schlafenderhase.com). This statement underscores how blending human review with automated checking allows RA teams to sign off on artwork with greater speed and assurance. In other words, AZ shows that when content teams own final accuracy but empower themselves with tools, the proofreading function is a shared, streamlined responsibility rather than a bottleneck.

ClinTrak (Speeding Clinical Trial Labeling)

ClinTrak (now Fisher Clinical Labeling Services) processes packaging for clinical trials in multiple languages. In 2009 they saw a need to scale up. Traditionally, their Document Quality Control inspectors would manually compare each draft label proof to the approved text **character-by-character**, a process taking up to *3–7 hours per 19-panel insert* ([12] www.healthcarepackaging.com). After deploying text-inspection and visual proofing systems from GlobalVision, ClinTrak saw dramatic improvements: they reduced the booklet proofing time to ~1.25 hours ([12] www.healthcarepackaging.com), and the tools caught foreign-character mismatches and even font differences invisible to the human eye. Stratifying: one ClinTrak QA said, *"The Global Vision solutions allowed the proofreading time for a 19-panel booklet to decrease from three to seven hours to about an hour-and-a-quarter."* ([12] www.healthcarepackaging.com). While ClinTrak's process insisted on **Regulatory sign-off** (clients reviewed proofs), this example illustrates how advanced QA scanning shifts the manual burden and lets RA reviewers focus on substantive content rather than grunt-proofing.

Packaging/Labeling Recall Cases

Concrete examples of labeling oversights underscore the human cost. Medical device manufacturers see ~10% of recalls due to labeling mix-ups ([8] packagingeurope.com). A topical case (not pharma but illustrative) involved an outer carton listing the wrong drug strength, while the inner contents were correct – a printing mismatch leading regulators to require a recall ([43] www.schlafenderhase.com). In pharmaceuticals, mislabeling incidents (such as strength or e-label mixups) have similarly jeopardized safety. Even consumer items show risk: Horehound cough syrup in the UK was once recalled when children's doses were printed incorrectly (a misplaced "." in a 0.5 mL syringe) – a proofreading error in packaging design with real health implications. While specific pharma case studies are often confidential, industry analyses repeatedly point to *typos and content errors* as the root of many recalls ([2] www.globalvision.co).

Collectively, these cases reveal that small mistakes can unravel huge efforts. They also tell us **who was involved**: a missed comma or wrong dosage can result from either the writer not catching it or the designer missing it. Thus, they argue for distributed checks: no one group "owns" quality alone; rather, multiple groups own parts of it.

Technologies and Modern Solutions

Automation Tools: With rising error rates and recall costs, technology solutions have received attention. Systems that compare an "approved master" vs. a "proof copy" are now common. These include:

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- **Text Comparators** (OCR or native-text comparators): Automatically flag any differences in wording, font, or line breaks. For example, GlobalVision's *Docu-Proof* and *ProofCheck* tools, or Schlafender Hase's TVT, use algorithms to highlight missing words or changes ([44] www.healthcarepackaging.com) ([24] www.imageprovision.com). They can handle multiple languages, character sets, and deliver audit reports.

- **Graphic Overlays / Vision Systems:** These take images of printed labels and overlay them with approved art, showing pixel-level deviations. ClinTrak used GlobalVision *Proofreader* cameras to inspect printed booklets, catching missing graphics or color shifts ([45] www.healthcarepackaging.com). Medical device firms deploy vision systems at print time to verify every label field ([46] packagingeurope.com).

- **Integrated Label Management Platforms:** Enterprise software (Veeva, Loftware, Esko, etc.) manages label content and workflow. These platforms enforce a single source of brand and regulatory content, automate version control, and sometimes incorporate "smart" proofreading by comparing data fields across countries ([47] packagingeurope.com). The trend is toward **lowering manual handoffs** – for instance, printing labels "just in time" at packaging and scanning barcodes in production to ensure right label meets right product ([48] packagingeurope.com) ([49] packagingeurope.com).

- **AI and Machine Learning:** Recently, Generative AI has entered the scene. Platforms like Appian propose AI-driven content analysis: from generating draft label copy to summarizing CCDS documents or checking label updates against safety signals ([50] appian.com) ([51] appian.com). AI models can flag inconsistent doses or cross-linguistic mismatches. However, industry experts caution that *"the problem isn't the AI. It's how pharma companies are using AI."* The emphasis is on embedding AI into the overall process, not treating it as a standalone proofreader ([52] appian.com) ([53] appian.com). Early adopters use AI to *augment* rather than replace human proofreaders, automating repetitive checks while alerting humans to ambiguous cases.

Process Integration: Perhaps more critical than any individual tool is how these are integrated. Pharma companies are centralizing labeling verification to avoid the "email/PDF mess" of the past ([36] www.schlafenderhase.com). Best practices involve:

- **Single Source of Truth:** Maintaining approved text in databases (e.g. Regulatory Information Management systems) that feed into artwork, and respective masters that go to print. For example, connecting labeling software directly to ERP to use live product master data, then tracking any changes through audit trails ([54] packagingeurope.com).

- **Geographically Distributed Teams:** Global pharma teams may have local "market colleagues" approve in-country labels. Effective systems ensure changes in one region automatically propagate to others with proper translation review flow ([22] informait.com).

- **Checks and Balances:** Standard procedures often require at least two people to sign off on final labels. An EU "Qualified Person" in labeling and packaging acts as a gatekeeper; GMP guidelines insist on parallel verification steps. The gmpsop manual (Table 2, Part 2) explicitly mandates that **"Market colleagues must receive the signed copies of the final artwork from the responsible market colleagues indicating [approval] by a multi-disciplinary (Medical, Legal, Regulatory, Marketing, Quality) review of the artwork content"** ([55] www.gmpsop.com). Simultaneously, the Artwork Center must ensure their final output has no discrepancies ([6] www.gmpsop.com).

Discussion: Ownership of Proofreading

Given this landscape, the **"Artwork vs. Text"** ownership question can be reframed: *It is a false dichotomy in a well-run organization*. Both sides must share accountability. In practice:

- **Text/Regulatory Perspective:** Because they provide the content and bear legal responsibility for its accuracy, RA/medical teams often lead textual proofreading. Internal SOPs usually require them to approve any wording changes and check the final layout to confirm no alterations. The Good Practice SOP explicitly states that Market/Regulatory colleagues are responsible for *"proofreading the new or revised artwork against the Editor's Copy"* ([4] www.gmpsop.com). Their checklist includes checking *literally every character and graphic element* ([4] www.gmpsop.com). In essence, the content experts own "right first time" accuracy of what is printed. If they sign off, they are attesting that the text is correct.

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- **Artwork/Graphic Perspective:** The design/production team owns the technical integrity of the file. They are responsible for preventing and detecting any errors introduced by software, fonts, or printing processes. For example, conversion errors (like a font mapping a "µg" to "mg" in Adobe Illustrator) are typical risks of artwork creation ([31] www.schlafenderhase.com). Artwork staff use proofing software to ensure the final PDF matches the approved source ([6] www.gmpsop.com). They also check printer proofs for color, bleed, and barcodes. While they rely on the content group to provide correct text, they insist on the right tools to verify that any **uncontrolled changes (graphics, barcodes, artwork)** did not slip in.
- **Bridging the Gap:** The brief from Schlafender Hase captures the reality: a "disconnect" between Reg Affairs and Artwork teams leads to errors and recalls ([56] www.schlafenderhase.com). The remedy is collaboration: *"Involve both teams early… standardize review processes… enforce strict version control… automate verification."* ([57] www.schlafenderhase.com). In fact, many companies now create multi-disciplinary review meetings or digital sign-offs to ensure alignment. In short, *"compliance is a team effort"* ([58] www.schlafenderhase.com).
- **Quality Assurance Perspective:** Ultimately, most organizations designate QA as the final checkpoint. QA does not originate content or create graphics, but they **own the release process**. This means any unresolved disagreement about content vs. design must be settled before QA approves the artwork. In practice, QA is the arbiter – they will require changes if either the content experts or designers indicate a discrepancy. Regulatory guidelines back this up by mandating written procedures for labeling issuance and reconciliation ([7] www.law.cornell.edu). The presence of QA sign-off effectively ties regulatory content accuracy to the artwork's fidelity.

Implications of Shared Ownership

The collaborative model has implications for responsibility and accountability:

- **Checks and Balances:** By involving multiple parties, the risk of a single oversight is mitigated, but no one party can shirk responsibility. For instance, if QA finds a missing warning that slipped through, blame could be traced to the responsible content reviewer who approved it, or the designer who omitted it. Clear documentation of who reviewed what (who "signed" the proof) is key.
- **SOP Clarity:** Organizations must **clearly document** each step in SOPs (often in RACI charts). Table 2 above outlines such roles. If the SOP says "Regulatory signs off on content, then Art team checks layout, then QA finalizes," everyone knows their part. In practice, companies often include language like "Market colleagues shall not approve artwork if further changes are expected" ([59] www.gmpsop.com), enforcing discipline that reduces semi-responsibility scenarios.
- **Skill and Resource Allocation:** Because proofreading touches expensive resources, companies weigh how to staff it. At one extreme, hiring highly trained scientists as proof-readers is wasteful ([1] www.schlafenderhase.com). At the other, entrusting it entirely to junior editors risks missing nuance. The trend is to reserve final content approval to experts (RA/Medical) but automate the mechanical task of comparison. This frees experts from copying tasks while ensuring they have vetted the key decisions.
- **Cross-Training and Culture:** An integrated proofreading process fosters mutual respect. Art teams must appreciate the content accuracy needs; RA teams must respect design constraints. Some organizations rotate people through each other's departments or hold joint reviews, blurring the strict "this is my job" stance. Schlafender Hase's advice ("compliance might be serious business but it doesn't have to feel like swimming against the tide" ([58] www.schlafenderhase.com)) reflects this more collegial approach.

Financial and Quality Implications

Failure to clearly resolve proofreading ownership has real costs:

- **Recall Costs:** Recalls are enormously expensive. Beyond remediation and product loss, companies suffer fines and reputational damage. The earlier-noted 2018 statistic (almost 10% of device recalls due to labeling issues ([8] packagingeurope.com)) reflects both unnecessary product loss and regulatory penalties.

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- **Workflow Efficiency:** Ambiguous responsibility can slow approvals. If Regulatory and Artwork keep passing files back and forth to catch each other's mistakes, every launch is delayed. In a competitive industry, delays in labeling in turn delay product launches, costing market share. Automating and defining ownership speeds time-to-market (high RFT – Right First Time – metrics, as the Freyr blog emphasizes ([60] www.freyrsolutions.com)).
- **Employee Morale and Turnover:** Repetitive manual proofreading is monotonous and error-prone ([1] www.schlafenderhase.com). Using senior scientists for manual proofing leads to burnout. The 2017 analysis bluntly notes that *"people are expensive"* and using their time for mundane tasks is poor ROI ([42] www.schlafenderhase.com). Clear role definitions and automation let skilled staff focus on value-added work. Conversely, if one team feels burdened unfairly, it creates internal friction.
- **Quality Culture:** A well-defined workflow with clear final authority (often QA) fosters a quality-conscious culture. If everyone knows who must approve what, and that lapses have consequences, errors drop. Companies that move to a centralized **Artwork Center of Excellence (CoE)** model – combining regulatory, quality, and creative under one umbrella – report significant improvements in RFT and compliance ([15] www.freyrsolutions.com).

Future Trends and Implications

Digital Transformation: The future of proofreading in pharma will be shaped by digital platforms:

- **Regulatory Content Systems:** Single-source databases (Regulatory Information Management, eCTD repositories) will become more connected to artwork. For example, linking Veeva RIM with label management (as Appian demonstrated ([61] appian.com)) ensures label text is always up-to-date. Automated alerts can "fail proof" when an old label is used.
- **AI-Augmented Review:** Generative AI can pre-fill safety statements or translate labels, but the need for final human proofreading persists. Future systems may propose text edits or flag unusual changes (e.g., an AI model trained on thousands of labels might flag that a "10 mg" changed to "100 mg" as improbable). Crowd-sourced or machine-assisted proofreading could speed up reviews, but oversight remains key.
- **Electronic Labeling (e-labels):** As regulators push digital medication guides (QR codes, online leaflets), the definition of "proofing" expands. Companies must now ensure correctness of both printed and electronic labeling. However, electronic distribution also offers opportunities: corrections to e-labels can be deployed instantly, reducing recall scope. Yet any inconsistency (printed vs digital) can cause confusion.
- **Advanced Character Recognition:** Future proofreading may involve real-time scanners. For instance, cameras on packaging lines could auto-verify labels against masters as each box is packed, catching errors that slipped through human proofing. Blockchain or serialization (DSCSA compliant) also require 100% accuracy of printed data, pushing automated OCR verification as mandatory.
- **Regulatory Evolution:** New regulations (like EU's more stringent readability rules, or expanded DSCSA in US) will demand that font sizes, contrasts, and even Braille be checked. While current practice relies on PDF checks, going forward AI may simulate patient reading (checking if a visually impaired person could read the label). The more digital tasks become, the clearer it is that **responsibility** for proofreading will rest on the system's processes, not on a single person.

Conclusion

Who owns the proofreading step? In a modern pharma company, the answer is: *it depends on the process and roles, but essentially everyone* who contributes to the label. The content owners (Regulatory/Medical) carry the responsibility for textual accuracy; the artwork producers guarantee the fidelity of the final printed layout; quality assurance ensures that all internal controls are satisfied. Legal and marketing also have parts to play.

Rather than agonize over a single "owner," best practice is to adopt a **governance model** that explicitly delineates each party's duties and hand-offs in the proofreading workflow ([4] www.gmpsop.com) ([16] www.freyrsolutions.com). Many companies explicitly require a multi-disciplinary review – a 'paper trail' of

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approvals – so that by the time QA signs off, the artwork has been vetted from all angles ([55] www.gmpsop.com). This approach reflects reality: the risk of errors is too great to be left to one group's stewardship alone.

In essence, proofreading in pharma packaging is not a creative act nor a mere clerical task, but a critical **quality assurance function**, and it falls under the collective umbrella of a company's Quality System. The question of "Artwork vs. Text" misses the point that modern labeling quality is achieved through **integration of content and design processes**. Ultimately, pharmaceutical quality depends on synergy: the regulatory scientists, marketing professionals, designers, and quality officers must all **own** the check in tandem.

As one industry commentary sums up: *"Maintaining pristine packaging requires…prioritiz [ing] quality control, proofreading, and adherence to regulations"* ([19] www.globalvision.co). In other words, the ownership of proofreading belongs to the **company's quality culture and processes as a whole** – a shared effort rather than an individual's job title.

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